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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/575,500

**Applicant(s)**

ZHOU ET AL.

**Examiner**

DAVID EASTWOOD

**Art Unit**

4185

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/86)  
Paper No(s)/Mail Date 8/24/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 6-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Conlon et al (US 6409733)** in view of **Spector (US 5135222)**.

**Regarding Claim 1**, Conlon et al discloses a flexible specimen retrieval pouch having a flexible wall with a closed end and an open end capable of receiving biological materials. (Column 10, claim1).

What Conlon et al fails to disclose is a pouch wall with discontinuous serrations with slots through which a retrieval string, open spring, retrieval noose etc. can pass through.

However, Spector discloses a ball with a large opening where said opening is encircled with V shaped notches with eyelets which are well known and capable of having a retrieval string, open spring, retrieval noose etc. pass through. (Column 6, Claim 1 and 5).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Conlon et al with the teachings of Spector in order to improve the closure ability of the specimen pouch and to ease the retraction of said pouch from the patient.

**Regarding claim 6**, Conlon et al discloses a pouch where there is a noose adjacent to the open end for the purpose of constricting and substantially closing the open end of said pouch (Column 10, Claims 1b and 8b). It would have been obvious to one of ordinary skill in the art at the time of invention to manufacture the noose of materials such as macromolecule materials, compound materials or metal materials in order to ensure an inert material to ease biocompatibility.

**Regarding claim 7-10**, Conlon et al discloses a pouch which is of multilayer construction incorporating flexible metal meshes, thermo formed plastic meshes, polyurethane and fabrics (Column 6, Lines 14-23)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Conlon et al's invention by adding a shape memory alloy to the disclosed pouch in order to ease deployment in vivo.

**Regarding claim 11**, Conlon et al discloses a pouch where there is a noose adjacent to the open end for the purpose of constricting and substantially closing the

open end of said pouch (Column 10, Claims 1b and 8b). The noose and pouch are connected in front of the distant end of an inner sheath which is inside an outer sheath and is a connected via a slipknot (Fig.2 numbers 75, 77, 95, 25, and 26, Figure 8 number 97).

Regarding claim 13, Conlon et al discloses a pouch that once deployed is secured by a one way ratchet mechanism fixing the pouches position. (Fig. 5)

What Conlon et al does not disclose is that the mechanism for fixation of the inner sheath is an orientation button. Conlon et al shows that the one way ratchet mechanism is an equivalent structure known in the art. Therefore, because these two fixing mechanisms were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the orientation button for the one way ratchet mechanism.

2. Claims 2-5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Conlon et al (US 6409733)** in view of **Spector (US 5135222)**, as applied to claim 1 above and further in view of **Spaeth et al (US 5312416)**.

**Regarding claim 2-3**, what Conlon et al's invention, as modified by Spector fails to disclose is; an open and retrieval string which can save the changed shape and return to the original or near original shape when disentangled, and both being made of shape memory alloy wires, pieces and alloy spring steel.

However, Spaeth et al discloses a resilient or biased rim member may be disposed about the aperture or opening of the containment sac such that, when

withdrawn into the lumen of the introducer, the rim member will be compressed into a collapsed or closed configuration but when disposed out of the distal end of the introducer the rim member will resiliently or otherwise expand from such compressed configuration to an open configuration. Such resilient or biased rim member may be formed of plastic strip, spring metal wire, metal or metal alloys which exhibit super elastic properties such as certain shape memory alloys (e.g. nickel-titanium alloys), or any other suitable material having sufficient memory to achieve the desired opening function. (Column 2, lines 43-57) and a tether which is extendable through the lumen 16 of the introducer (column 6, lines 4-6) The tether may be attached to the rim member such that the rim member may swivel relative to the tether. Particularly, the distal end of the tether is wrapped about the rim member. (Column 6, lines 15-20)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the invention of Conlon et al, in view of Spector and Spaeth et al to produce a biological specimen retrieval device which would improve the closure ability of the specimen pouch and to ease the retraction of said pouch from the patient.

**Regarding claim 4-5**, Conlon et al's invention, as modified by Spector fails to disclose; an open spring which can save the changed shape and return to the original or near original shape when disentangled, and both being made of shape memory alloy wires, pieces and alloy spring steel.

However, Spaeth et al discloses a resilient or biased rim member may be disposed about the aperture or opening of the containment sac such that, when withdrawn into the lumen of the introducer, the rim member will be compressed into a

collapsed or closed configuration but when disposed out of the distal end of the introducer the rim member will resiliently or otherwise expand from such compressed configuration to an open configuration. Such resilient or biased rim member may be formed of plastic strip, spring metal wire, metal or metal alloys which exhibit super elastic properties such as certain shape memory alloys (e.g. nickel-titanium alloys), or any other suitable material having sufficient memory to achieve the desired opening function. (Column 2, lines 43-57) and a tether which is extendable through the lumen 16 of the introducer (column 6, lines 4-6) The tether may be attached to the rim member such that the rim member may swivel relative to the tether. Particularly, the distal end of the tether is wrapped about the rim member. (Column 6, lines 15-20)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the invention of Conlon et al, in view of Spector and Spaeth et al to produce a biological specimen retrieval device which would improve the closure ability of the specimen pouch and to ease the retraction of said pouch from the patient.

**Regarding claim 12**, Conlon et al discloses a pouch where there is a noose adjacent to the open end for the purpose of constricting and substantially closing the open end of said pouch (Column 10, Claims 1b and 8b). The noose and pouch are connected in front of the distant end of an inner sheath which is inside an outer sheath and is a connected via a slipknot (Fig. 2 numbers 75, 77, 95, 25, and 26, Figure 8 number 97).

It would have been obvious to one of ordinary skill in the art at the time of invention to loop the noose through the slots created by the serrated ends as disclosed

by Conlon et al as modified by Spector in further view of Spaeth et al in order to improve the closure ability of the specimen pouch and to ease the retraction of said pouch from the patient

3. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Conlon et al (US 6409733)** in view of **Spector (US 5135222)** and **Matey et al (US 5649021)**.

**Regarding Claim 14**, The invention of Conlon et al as modified by Spector disclose a flexible specimen retrieval pouch having a flexible wall with a closed end and an open end with a large opening where said opening is encircled with V shaped notches with eyelets which are well known and capable of having a retrieval string, open spring, retrieval noose etc. pass through and capable of receiving biological materials.

What Conlon et al and spector fail to disclose is a specimen pouch with an open end that is colored distinctly from the biological specimen observed under endoscopic equipment.

However, Matey et al discloses a laparoscopic tool having a unique color marker not found on the interior of the abdomen (Column 3, Lines 55-59). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Conlon et al's invention by coloring the open end of the biological specimen pouch such that it could be distinguished from the surrounding tissue in vivo.

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pagedas, Anthony (US 5368597), Kammerer et al. (US 5480404), Kindberg et al. (US RE35164), Yoon, InBae (US 5755724), Riek et al (US



5895392), Middleman et al. (US 6004330), Bennardo, Roberto (US6206889), Pagedas, Anthony C. (US 6258102), Conlon et al (US 6383197), Stefanchik, David (US 6406440).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571)2724797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID EASTWOOD/  
Examiner, Art Unit 4185  
**/Terrell L McKinnon/  
Supervisory Patent Examiner, Art Unit 4185**

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